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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,588	01/16/2001	Melton B. Affrime	AL01132K	4299

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,588	AFFRIME ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-20,22-25,27-39,41-46,48,49 and 51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *19-20, 22-23, 29,30 and 61-64* is/are allowed.

6)☒ Claim(s) *1-9,11-18,24,25,27,28,31-39,41-46,48,49 and 51-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The following is responsive to Applicant's amendment received Aug. 26, 2002.

Claims 10, 21, 26, 40, 47 and 50 are cancelled without prejudice.

New claims 60-64 are added.

Claims 1-9, 11-20, 22-25, 27-39, 41-46, 48-49, 51-64 are currently pending.

The previous claims objection, set forth in paragraph 2 of the office action mailed Feb. 27, 2002, is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claims rejections under 35 USC 112, paragraph 2, set forth in paragraphs 3-26 of the office action mailed Feb. 27, 2002, are withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claims rejection under 35 USC 103(a) set forth in paragraphs 27-29 of the office action mailed Feb. 27, 2002 is withdrawn in view of the new ground of rejection submitted below.

New Ground of Rejection

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-9, 11-18, 24-25, 27-28, 31-39, 41-46, 48-49, 51-59, 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handley et al., 5,962,464 and Aberg et al., 5,595,997 in view of Padhi et al. (abstract) and Herron et al. (abstract).

Handley et al. disclose methods for treating allergic disorders such as allergic asthma, urticaria, allergic rhinitis and atopic dermatitis comprising administering a therapeutically

effective amount of descarboethoxyloratadine (DCL) otherwise known as desloratadine. The methods also involve treating symptoms associated with allergic rhinitis such as sneezing, lacrimation, rhinorrhea comprising administering an effective amount of DCL. The pharmaceutical compositions containing DCL are administered (in single or divided doses) in an amount of .1mg to less than about 10 mg, preferably ranging from about .1 to 5 mg. Please see the abstract; col. 4, lines 44-50col. 5, lines 30-47; col. 6, lines 13-18; col. 6, lines 55-60.

Aberg et al., disclose methods of treating allergic asthma, allergic rhinitis or urticaria in a human, the methods comprising administering effective amounts of DCL. The amounts of DCL may range from .1 mg to less than about 10 mg, with a preferred dosage ranging from .1 to 5 mg. Please see the abstract; col. 4, lines 34-44; col. 5, lines 48-54; col. 7, lines 33-38; col. 8, lines 19-43.

Handley and Aberg do not specifically disclose Applicant's claimed geometric mean steady state and arithmetic mean steady state plasma concentrations nor do Handley and Aberg disclose administering DCL twice a day at 2.5 mg; however, the Examiner refers to Padhi et al. and Herron et al. which study the pharmacokinetics of desloratadine in healthy adult volunteers. Padhi and Herron et al. disclose orally administering effective amounts of desloratadine (5, 7.5, 10 or 20 mg) to adult volunteers and then determining the plasma concentrations by looking at Cmax and AUC values. Padhi and Herron et al. disclose that desloratadine was safe and well tolerated and that desloratadine exhibited a linear pharmacokinetics over the dose range of 5 to

20 mg and further that such linearity implies predictability in the pharmacokinetics of desloratadine. Please refer to the abstracts.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Handley and Aberg to administer desloratadine such that the claimed plasma concentrations are achieved because Padhi and Herron et al. raise reasonable expectation of success by establishing that there is a correlation between the efficacy and tolerability of desloratadine and it's pharmacokinetics, i.e. Cmax and AUC values. One of ordinary skill in the art would be motivated to administer desloratadine at an amount which results in optimum plasma values thus rendering desloratadine efficacious and safe in treatments of patients suffering from allergic disorders.

Moreover, absent evidence to the contrary, since Handley, Aberg, Padhi and Herron establish that the efficacy of desloratadine is dependent upon its dosage, it would have been obvious to one of ordinary skill in the art to further modify the methods of Handley and Aberg such that desloratadine is administered in an amount and for a time that is effective to optimize its effect on the allergic disorders being treated. Such a modification would have been motivated by the reasoned expectation of effectively treating or preventing allergic disorders.

With respect to the plasma concentrations of 3-OH-desloratadine, this would have been obvious in the prior art since 3-OH is a natural metabolite of deloratadine.

Finally, with respect to treating a human of 12 years or older, since the both Handley and Aberg disclose treating "humans" in general, one of ordinary skill in the art would reasonably

expect human patients of 12 years or older to benefit from the treatment methods of Handley and Aberg.

Allowable Subject Matter

Claims 19-20, 22, 23, 29, 30, 61-64 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed method.

Conclusion

Claims 1-9, 11-18, 24-25, 27-28, 31-39, 41-46, 48-49, 51-59, 60 are rejected.

4. Applicant's submission of an information disclosure statement under 37 CFR 1.97© with the fee set forth in 37 CFR 1.17(p) on Aug. 26, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 609(B)(2)(I). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Nov. 17, 2002